



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-day comment request

National Children's Study (NCS) Data and Sample Archive and Access System

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on April 22, 2015, Vol.80, No. 77 and allowed 60 days for public comment. One public comment was received. The purpose of this notice is to allow an additional 30 days for public comment. The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Ms. Sarah L. Glavin, Deputy Director, Office of Science Policy, Analysis and Communication, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 31 Center Drive, Room 2A18, Bethesda, Maryland 20892, or call a non-toll free number (301) 496-7898 or Email your request, including your address to glavins@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION: National Children's Study (NCS) Data and Sample Archive and Access System, 0925-NEW, National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH).

Need and Use of Information Collection: The primary use of this information collected from potential users of the NCS Data and Sample Archive and Access System is to document, track, and monitor its use. The purpose of the archive is to share data collected in the NCS Vanguard (OMB # 0925-0593) with qualified users. Users will provide basic contact information, complete brief data user training, and agree to terms and conditions of data and archive use prior to accessing any data. A Research Plan describing the information and materials requested will also be required for access to certain types of research materials. This information is necessary to fulfill the requirements of the proposed research projects and will help NIH understand and

evaluate the use of archived data and samples by the research community.

OMB approval is requested for three years. There are no costs to respondents other than their time.

The total estimated annualized burden hours are 109.

Estimated Annualized Burden Hours

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Form	Number of Respondents	Frequency of Response	Average Time Per Response (in hours)	Total Annual Burden Hours
Vanguard Downloadable Data Access Form (Attachment A.1)	300	1	10/60	50
Vanguard Data Request Form (Attachment A.2)	50	1	20/60	17
Vanguard Specimen and Data Request Form (Attachment A.3)	50	1	30/60	25
Research Materials Distribution Agreement (Attachment A.4)	100	1	10/60	17

Dated: August 26, 2015

Sarah L. Glavin, Ph.D.

Project Clearance Officer, Eunice Kennedy Shriver National Institute of Child Health and Human Development, Deputy Director, Office of Science Policy, Analysis, and Communications, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health

[FR Doc. 2015-22006 Filed: 9/3/2015 08:45 am; Publication Date: 9/4/2015]